

I. REMARKS

Upon entry of the foregoing amendment, claims 1-15 and 17-27 are pending in the present application. Claim 16 is cancelled. Claims 19-27 stand withdrawn.

Claims 1, 10, 11 and 15 are currently amended. Basis for the amendments to claims 1 and 15 may be found at page 4, 3rd paragraph of the present specification. Claims 10 and 11 have been amended solely to overcome the Examiner's allegation of indefiniteness on page 5 regarding claims 11 and 12. The amendment makes it clear that the epimerically enriched compound is the starting material. Applicant, by canceling or amending any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicant reserves the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application. It is believed this amendment does not introduce new matter and entry is respectfully requested.

Applicant notes the Examiner's statement in the Official Action that applicants have not complied with the priority requirements under 35 USC §120. However, applicant notes that an appropriate Application Data Sheet was submitted and that no claim to priority under §120 has been filed. This application was filed as a national stage application under 35 U.S.C. §371.

II. OBJECTION TO CLAIMS 10 AND 13

At page 4 of the Official Action, the Examiner has objected to claims 10 and 13 for allegedly not limiting the claims from which they depend.

Applicant respectfully traverses and directs the Examiner's attention to the specification at page 3, which states, in relevant part,

"The compound of formula I is a compound with the chemical name 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxo-propoxy)pregna-1,4-diene-3,20-dione [11beta, 16alpha (R,S)]. The R-epimer (based on the absolute configuration at C-22) of this compound has the INN...ciclesonide. The term compound of the formula I encompasses according to the invention the pure R epimer, the pure S epimer and R/S epimer mixtures in any mixing ration and also pharmaceutically acceptable solvates of the compound of the formula I."

As such, it is clear that claim 10 specifies the compound of the formula I as being an equal (50:50) mixture of the S- and R-epimer of the compound of the formula I, whereas claim 13 limits claim 1 to the pure R-epimer only (which has the INN ciclesonide). The last sentence of the above paragraph of the specification makes it quite clear to a person of ordinary skill in the art that the compound of the formula I can comprise different sub-groups, each characterized by different ratios of the respective epimers. These different sub-groups are the subject matter of claims 10 and 13 and therefore should not be objected to since they do indeed limit the scope of the claim from which they depend.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this objection to claims 10 and 13.

III. REJECTION UNDER 35 U.S.C. §112, 2ND PARAGRAPH

At page 4 of the Official Action, the Examiner has rejected claims 11 and 12 under 35 U.S.C. §112, 2nd paragraph as being indefinite.

Applicant respectfully traverses. However, solely to remove the basis for this rejection, applicant has amended claim 11 herein to make it clear that the epimerically enriched compound is the starting material.

Claim 12 has not been amended as it depends from claim 11, thereby incorporating the limitations of claim 11.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection of claims 11 and 12.

IV. REJECTION UNDER 35 USC § 103(a)

At page 6 of the Official Action, the Examiner has rejected claims 1-18 under 35 USC § 103(a) as being unpatentable over Amschler (WO98/09982).

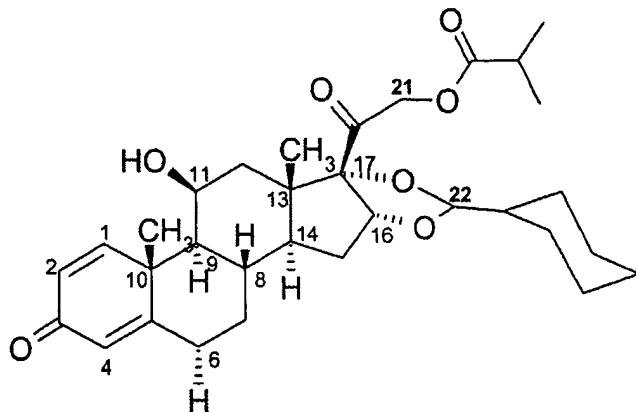
The rejection is respectfully traversed. The Examiner has not established a *prima facie* case of obviousness against the presently pending claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, there must be some motivation or teaching in the references

cited by the Examiner to combine the separate elements taught in the separate references. As the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." See *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Presently pending claim 1 is directed to a process for preparing a compound of

the formula I



Formula I

in crystalline form, with a particle diameter for 50% of the total volume of all particles (X_{50}) of less than or equal to $3\mu\text{m}$, comprising the steps of

- a) preparing a solution of the compound of the formula I in a suitable water-miscible organic solvent;
- b) adding the solution obtained in a) to water and
- c) isolating a precipitate of the compound of the formula I which is formed.

Despite clear evidence to the contrary contained in applicant's disclosure, the Examiner has alleged that the '982 publication would make the claimed process obvious under 35 U.S.C. §103(a). In this regard, applicant respectfully directs the Examiner's attention to page 11 of the instant specification, Example 3. In Example 3, applicant has clearly indicated that the process disclosed in the '982 publication

yields much higher X_{50} values than those presently claimed. In particular, Examples 1-6 (listed under Example 3) all yield X_{50} values over 20 μ m. Applicant further respectfully directs the Examiner's attention to the last sentence of Example 3 which states that such X_{50} values "are not in the range of X_{50} values of particle sizes suitable for inhalation." As such, the '982 publication teaches away from the presently pending claims. Further, applicant respectfully notes that the '982 publication has no teaching whatsoever regarding how to arrive at the presently claimed particle diameter.

As such, the '982 publication cannot possibly render the presently claimed process obvious.

The Examiner also cites the Merck Manual (1996). Actually, the Examiner provided a copy of the Merck Index from 1996. This reference clearly does not remedy the deficient teachings of the '982 publication as it has no teaching regarding the presently claimed particle diameter.

Thus, the references cited by the Examiner cannot possibly render the presently pending claims obvious. As outlined above, the references of record contain absolutely no teaching of the presently pending claims.

Accordingly, the presently rejected claims are unobvious over the cited references and withdrawal of this rejection is respectfully requested.

III. CONCLUSION

Applicant asserts that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicant's undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



Joshua B. Goldberg
Registration No. 44,126
Sheldon M. McGee
Registration No. 50,454
Customer No. 34375

Date: August 27, 2009
THE NATH LAW GROUP
112 South West Street
Alexandria, Virginia 22314
Tel: (703) 548-6284
Fax: (703) 683-8396
JBG/SMM/ROA.doc